

§ 201.315

drug application or abbreviated new drug application.

(ii) Compliance by April 19, 2004, for OTC antidiarrheal and overindulgence drug products that contain bismuth subsalicylate as an active ingredient and have annual sales greater than \$25,000.

(iii) Compliance by April 18, 2005, for OTC antidiarrheal and overindulgence drug products that contain bismuth subsalicylate as an active ingredient and have annual sales less than \$25,000.

(iv) Compliance dates for all other OTC drug products containing aspirin and nonaspirin salicylates as an active ingredient and marketed under an OTC drug monograph (for internal analgesic, antipyretic, and antirheumatic drug products, or for menstrual drug products) will be established when the final monographs for those products are published in a future issue of the FEDERAL REGISTER. In the interim, these products should continue to be labeled with the previous Reye's syndrome warning that appears in paragraph (h)(1) of this section.

[40 FR 13998, Mar. 27, 1985, as amended at 51 FR 8182, Mar. 7, 1986; 53 FR 21637, June 9, 1988; 53 FR 24830, June 30, 1988; 64 FR 13291, Mar. 17, 1999; 65 FR 8, Jan. 3, 2000; 68 FR 18869, Apr. 17, 2003]

§ 201.315 Over-the-counter drugs for minor sore throats; suggested warning.

The Food and Drug Administration has studied the problem of the labeling of lozenges or troches containing a local anesthetic, chewing gum containing aspirin, various mouth washes and gargles and other articles sold over the counter for the relief of minor irritations of the mouth or throat. It will not object to the labeling of suitable articles of this type "For the temporary relief of minor sore throats", provided this is immediately followed in the labeling with a warning statement in prominent type essentially as follows: "Warning—Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult physician promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by physician."

21 CFR Ch. I (4–1–05 Edition)

§ 201.316 Drugs with thyroid hormone activity for human use; required warning.

(a) Drugs with thyroid hormone activity have been promoted for, and continue to be dispensed and prescribed for, use in the treatment of obesity, although their safety and effectiveness for that use have never been established.

(b) Drugs for human use with thyroid hormone activity are misbranded within the meaning of section 502 of the Federal Food, Drug, and Cosmetic Act unless their labeling bears the following boxed warning at the beginning of the "Warnings" section:

Drugs with thyroid hormone activity, alone or together with other therapeutic agents, have been used for the treatment of obesity. In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life-threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

[43 FR 22009, May 23, 1978]

§ 201.317 Digitalis and related cardiotonic drugs for human use in oral dosage forms; required warning.

(a) Digitalis and related cardiotonic drugs for human use in oral dosage forms have been promoted for, and continue to be dispensed and prescribed for, use in the treatment of obesity, although their safety and effectiveness for that use have never been established.

(b) Digitalis and related cardiotonic drugs for human use in oral dosage forms are misbranded within the meaning of section 502 of the Federal Food, Drug, and Cosmetic Act unless their labeling bears the following boxed warning at the beginning of the "Warnings" section: